SPECIAL eBULLETIN

AUGUST 2020

JULY/AUGUST 2020 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the update to the Highmark Drug Formularies and pharmaceutical management procedures for July/August 2020. The formularies and pharmaceutical management procedures are updated on a bimonthly basis, and the following changes reflect the decisions made in June 2020 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via NaviNet® or our website). Click the **Pharmacy Program/Formularies** link from the menu on the left.

HIGHMARK.

Important Drug Safety Updates

Update: Health Professional and Consumer on Recent Recalled Products Due to Detection of Impurities and Potential Risk of Cancer

As part of an ongoing investigation into the voluntary recall of products due to the detection of probable human carcinogen impurities and increased risk of cancer, there were two additional voluntary recalls. Health care professionals should be aware that the recalled products pose an unnecessary risk to patients.

Pharmacists and physicians may direct patients to alternative treatment prior to returning to their medications. Physicians should evaluate the risk versus the benefit if treatment is stopped immediately, as stopping treatment immediately without alternative treatment may lead to a higher risk of harm to the patient's health.

The additional products that have been recalled due to the impurities are listed below. Not all products from all the manufacturers are recalled. Patients and physicians should check the FDA website to see if the lot number of their medication has been included in the recall.

Manufacturer	Recalled Drugs	Detected Impurity
Amneal Pharmaceuticals, LLC	Nizatidine Oral Solution, 15 mg/mL	N-Nitrosodimethylamine (NDMA)
Apotex Corp	Metformin Hydrochloride 500 mg Extended-Release Tablets	N-Nitrosodimethylamine (NDMA)
Amneal Pharmaceuticals, LLC	Metformin Hydrochloride Extended-Release 500 mg and 750 mg tablets	N-Nitrosodimethylamine (NDMA)
Teva Pharmaceuticals USA, Inc	Metformin Hydrochloride Extended-Release 500 mg and 750 mg tablets	N-Nitrosodimethylamine (NDMA)
Marksans Pharma Limited	Metformin Hydrochloride 500 mg Extended-Release Tablets	N-Nitrosodimethylamine (NDMA)
Lupin Pharmaceuticals Inc	Metformin Hydrochloride 500 mg Extended-Release Tablets	N-Nitrosodimethylamine (NDMA)

Tetracycline 250 mg and 500 mg capsules by Avet Pharmaceuticals: Recall – Low dissolution results

On April 16, 2020, Avet Pharmaceuticals Inc. recalled eight lots of Tetracycline 250 and 500 mg capsules. The affected product was recalled due to low out of specification dissolution test results.

Low dissolution results in less tetracycline available in the body to fight infection. This can lead to treatment failures. For patients with compromised immune systems and the elderly, who may be taking tetracycline to treat a serious infection such as pneumonia, there is a reasonable probability that if there is not enough tetracycline in the body to fight the infection, this could result in rapid progression of the infection and death. To date, Avet has not received adverse event reports or complaints related to this event.

Ketorolac Tromethamine 30 mg/mL and 60 mg/2 mL Injections by Fresenius Kabi USA, LLC: Recall – Presence of particulate matter

On April 20, 2020, Fresenius Kabi USA, LLC recalled thirteen lots of Ketorolac Tromethamine 30 mg/mL and 60 mg/2 mL Injections. The affected product was recalled due to the presence of particulate matter composed of the following elements: carbon, silicon, oxygen, and polyamides.

Administration of products containing particulate matter could obstruct blood vessels and result in local irritation of blood vessels, swelling at the site of injection, a mass of tissue that could become inflamed and infected, blood clots traveling to the lung, scarring of the lung tissues, and allergic reactions that could lead to life-threatening consequences.

NP Thyroid 30 mg, 60 mg, and 90 mg by Acella Pharmaceuticals LLC: Recall – Super potency

On May 22, 2020, Acella Pharmaceuticals, LLC recalled thirteen lots of NP Thyroid 30 mg, 60 mg, and 90 mg. The affected product was recalled because testing has found these lots to be super potent.

Patients being treated for hypothyroidism (underactive thyroid), who receive super potent NP Thyroid, may experience signs and symptoms of hyperthyroidism (overactive thyroid) which include, but are not limited to, weight loss, heat intolerance, fatigue, muscle weakness, hypertension, chest pain, rapid heart rate, or heart rhythm disturbances. Pregnant women who take super potent NP Thyroid may also experience negative maternal and fetal outcomes including miscarriage and/or impairment to fetal development. Patients should talk to their health care professional before they stop taking their NP Thyroid medicine. To date, Acella has received two reports of adverse events known to be related to this recall.

Hydroxychloroquine and chloroquine: Drug Safety Communications – FDA cautions against the use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems

On April 24, 2020, the FDA reported risk of serious heart rhythm problems in patients with COVID-19 treated with hydroxychloroquine or chloroquine, often in combination with azithromycin and other QT prolonging medicines.

Hydroxychloroquine and chloroquine have not been shown to be safe and effective for treating or preventing COVID-19. They are being studied in clinical trials for COVID-19, and the FDA had authorized their temporary use during the COVID-19 pandemic for treatment of the virus in hospitalized patients when clinical trials are not available, or participation is not feasible, through an Emergency Use Authorization (EUA).

As of June 15, 2020, the FDA has revoked the emergency use authorization (EUA) to use hydroxychloroquine and chloroquine to treat COVID-19 in certain hospitalized patients when a clinical trial is unavailable or participation is not feasible. They made this determination based on recent results from a large, randomized clinical trial in hospitalized patients that found these medicines showed no benefit for decreasing the likelihood of death or speeding

recovery. This outcome was consistent with other new data, including those showing the suggested dosing for these medicines are unlikely to kill or inhibit the virus that causes COVID-19. As a result, the FDA has determined that the legal criteria for the EUA are no longer met.

Please refer to the Revocation of the EUA Letter and FAQs on the Revocation of the EUA for Hydroxychloroquine Sulfate and Chloroquine Phosphate for more information.

Highmark Formulary Update – July 2020

SECTION I. Highmark Commercial and Healthcare Reform Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Comprehensive Healthcare Reform Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. Please note that the Highmark Comprehensive Closed/Incentive Formulary is a complete subset of the Open Formulary; therefore, all medications added to the Comprehensive Closed/Incentive Formulary are also added to the Open Formulary. These updates are effective on the dates noted throughout this document. For your convenience, you can search the following formularies online:

Highmark Comprehensive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=8103967260)

Highmark Comprehensive Healthcare Reform Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4906449921)

Highmark is happy to inform you that Table 1 includes products that have been added to the formulary. Adding products to the formulary may mean lower copays or coinsurance rates for members. By adding products to the formulary, Highmark hopes to promote adherence to medication protocols and improve the overall health of our members.

Table 1. Products Added
(All products added to the formulary effective July 4, 2020, unless otherwise noted.)

Brand Name	Generic Name	Comments
Tukysa	tucatinib	For use in combination with trastuzumab and capecitabine for treatment of patients with advanced or metastatic HER2-positive breast cancer.

*Effective date to be determined.
Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Bafiertam*	monomethyl fumarate	Tecfidera
MenQuadfi vaccine*	meningococcal (Groups A, C, Y, W) conjugate vaccine	Menveo, Menactra
Milprosa vaginal ring*	progesterone vaginal ring	Crinone, Endometrin
Ongentys*	opicapone	entacapone
Zeposia 0.92 mg Capsule, Starter Kit, and Starter Pack	ozanimod 0.92 mg Capsule, Starter Kit, and Starter Pack	Gilenya, Mayzent
Isturisa	osilodrostat	Provider Discretion
Koselugo 10 mg and 25 mg	(selumetinib) 10 mg and 25 mg	Provider Discretion
Pemazyre	(pemigatinib)	Provider Discretion

Brand Name	Generic Name	Preferred Alternatives
Sevenfact*	(coagulation factor VIIa [recombinant]-jncw)	Provider Discretion

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
Physicians may request coverage of these products using the Prescription Drug Medication Request Form, which can be accessed online in Highmark's Provider Resource Center. Under **Provider Forms, select **Miscellaneous Forms**, and then select the form titled **Request for Non-Formulary Drug Coverage**.

Table 3. Additions to the Specialty Tier Copay Option

Note: The specialty tier does not apply to Highmark Delaware Healthcare Reform members; see Highmark Delaware's online Provider Resource Center and access the **Pharmacy Program/ Formularies** link for details on the formularies and formulary options that apply to Highmark Delaware Healthcare Reform members.

(Effective upon completion of internal review and implementation unless otherwise noted.)

Brand Name	Generic Name
Bafiertam	monomethyl fumarate
Tukysa	tucatinib
Zeposia 0.92 mg Capsule, Starter Kit, and Starter Pack	ozanimod 0.92 mg Capsule, Starter Kit, and Starter Pack
Isturisa	osilodrostat
Koselugo 10 mg and 25 mg	selumetinib 10 mg and 25 mg
Pemazyre	Pemigatinib
Sevenfact	coagulation factor VIIa [recombinant]-jncw

Table 4. Products to Be Removed or Shifted to Higher Tier—Effective October 1, 2020

Brand name	Generic Name	Preferred Alternatives
Only Healthcare Reform Comprehensive Products		
adapalene	adapalene	tretinoin, Differin Gel OTC
cimetidine	cimetidine	cimetidine OTC, famotidine
diphenhydramine HCl	diphenhydramine HCl	diphenhydramine OTC, children's allergy relief OTC
fexofenadine HCl	fexofenadine HCl	fexofenadine OTC
Glydo	lidocaine HCl	pain relief with lidocaine OTC, Aspercreme with lidocaine OTC
levocarnitine	levocarnitine (with sugar)	levocarnitine OTC
lidocaine 5% ointment	lidocaine	lidocaine 5% cream OTC, Topicaine 5% gel OTC
lidocaine 5% patch	lidocaine	lidocaine pain relief patch OTC, Aspercreme patch OTC
lidocaine HCl 2% jelly	lidocaine HCl	pain relief with lidocaine OTC, Aspercreme with lidocaine OTC
lidocaine HCl 3% lotion	lidocaine 3% cream OTC	
Lido-K	lidocaine HCl	lidocaine 3% cream OTC
Lidozion	lidocaine HCl	lidocaine 3% cream OTC

Brand name	Generic Name	Preferred Alternatives
metformin HCl ER	metformin HCl	metformin HCl ER (generic glucophage XR)
niacin ER	niacin	niacin ER OTC, Slo-Niacin OTC
phenazopyridine HCl	phenazopyridine HCl	AZO Urinary Pain Relief OTC
ranitidine HCl	ranitidine HCl	cimetidine OTC, famotidine
Only Commercial Comprehensive Products		
Loprox	ciclopirox/skin cleanser no.40	ciclopirox
All Commercial & Healthcare Reform Comprehensive Products		
Advair Diskus	fluticasone propion/salmeterol	fluticasone-salmeterol, Wixela Inhub
Afinitor	everolimus	everolimus
Apriso	mesalamine	mesalamine ER
Carafate	sucralfate	sucralfate
Daraprim	pyrimethamine	pyrimethamine
Depen	penicillamine	penicillamine
Diastat	diazepam	diazepam
Differin	adapalene	tretinoin, Differin Gel OTC
Dyrenium	triamterene	triamterene
heparin sodium in 0.45% NaCl	heparin sod,pork in 0.45% NaCl	heparin sodium in 0.45% NaCl
Lido-Sorb	lidocaine HCl	lidocaine 3% cream OTC
manganese sulfate	manganese sulfate	Provider Discretion
Nebupent	pentamidine isethionate	pentamidine isethionate
Nuvaring	etonogestrel/ethinyl estradiol	Eluryng, etonogestrel-ethinyl estradiol
Orfadin	nitisinone	nitisinone
Proair HFA	albuterol sulfate	albuterol sulfate HFA
Samsca	tolvaptan	tolvaptan
Transderm-Scop	scopolamine	scopolamine
Travatan Z	travoprost	travoprost

B. Changes to the Highmark Progressive Formulary and the Highmark Healthcare Reform Progressive Formulary

Note: The Progressive Formulary does not apply to Highmark Delaware members; see Highmark Delaware's online Provider Resource Center and access the **Pharmacy Program/Formularies** link for details on the formularies and formulary options that apply to Highmark Delaware members. For your convenience, you may search the following formularies online:

Highmark Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=1176922773)

Highmark Healthcare Reform Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4909431197)

Table 1. Formulary Updates (All products added to the formulary effective July 4, 2020, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are preferred products			
Tukysa	tucatinib	3 - Preferred Specialty	For use in combination with trastuzumab and capecitabine for treatment of patients with advanced or metastatic HER2-positive breast cancer.
Items listed below are non-preferred products			
MenQuadfi vaccine*	meningococcal (Groups A, C, Y, W) conjugate vaccine	3 - Non-preferred Brand	Menveo, Menactra
Ongentys*	opicapone	3 - Non-preferred Brand	entacapone
Milprosa vaginal ring*	progesterone vaginal ring	3 - Non-preferred Brand	Provider Discretion
Bafiertam*	monomethyl fumarate	4 - Non-preferred Specialty	Tecfidera
Zeposia 0.92 mg Capsule	ozanimod 0.92 mg Capsule	4 - Non-preferred Specialty	Gilenya, Mayzent
Zeposia 7-Day Starter Kit	ozanimod 7-Day Starter Pack	4 - Non-preferred Specialty	Gilenya, Mayzent
Zeposia 7-Day Starter Pack	ozanimod 7-Day Starter Pack	4 - Non-preferred Specialty	Gilenya, Mayzent
Isturisa	osilodrostat	4 - Non-preferred Specialty	Provider Discretion
Koselugo 10 mg and 25 mg	selumetinib 10 mg and 25 mg	4 - Non-preferred Specialty	Provider Discretion
Pemazyre	pemigatinib	4 - Non-preferred Specialty	Provider Discretion
Sevenfact*	coagulation factor VIIa [recombinant]-jncw	4 - Non-preferred Specialty	Provider Discretion

Coverage may be contingent upon plan benefits.
*Effective date to be determined.
Tier 1: Preferred generic drugs; **Tier 2:** Preferred brand drugs; **Tier 3:** Non-preferred generic drugs, non-preferred brand drugs, preferred specialty drugs; **Tier 4:** Non-preferred specialty drugs.
Add any drug-specific information/exceptions in footnotes
e.g. † Preferred product only for commercial Progressive Formulary; does not apply to Progressive Healthcare Reform Formulary.

Table 2. Products to Be Removed or Shifted to Higher Tier –Effective October 1, 2020

Brand Name	Generic Name	Preferred Alternatives
Only Healthcare Reform Progressive Products		
adapalene	adapalene	tretinoin, Differin Gel OTC
Apriso	mesalamine	mesalamine ER
Benzepro	benzoyl peroxide	benzoyl peroxide OTC

Brand Name	Generic Name	Preferred Alternatives
benzoyl peroxide	benzoyl peroxide	benzoyl peroxide OTC
BPO	benzoyl peroxide	benzoyl peroxide OTC
Cimetidine	cimetidine	cimetidine OTC, famotidine
clotrimazole	clotrimazole	Lotrimin AF OTC, clotrimazole OTC
Depen	penicillamine	penicillamine
diclofenac sodium	diclofenac sodium	fluorouracil
diphenhydramine HCl	diphenhydramine HCl	diphenhydramine OTC, children's allergy relief OTC
Glydo	lidocaine HCl	pain relief with lidocaine OTC, Aspercreme with lidocaine OTC
levocarnitine	levocarnitine (with sugar)	levocarnitine OTC
levocetirizine dihydrochloride	levocetirizine dihydrochloride	Xyzal OTC
lidocaine 5% ointment	lidocaine	lidocaine 5% cream OTC, Topicaine 5% gel OTC
lidocaine HCl 2% Jel Urojet AC	lidocaine	pain relief with lidocaine OTC, Aspercreme with lidocaine OTC
lidocaine HCl 2% jelly	lidocaine	pain relief with lidocaine OTC, Aspercreme with lidocaine OTC
lidocaine HCl 3% lotion	lidocaine	lidocaine 3% cream OTC
Lido-K	lidocaine HCl	lidocaine 3% cream OTC
Lido-Sorb	lidocaine HCl	lidocaine 3% cream OTC
Lidozion	lidocaine HCl	lidocaine 3% cream OTC
loperamide HCl	loperamide HCl	Imodium A-D OTC , loperamide HCl OTC
metformin HCl ER	metformin HCl	metformin HCl ER (generic Glucophage XR)
Nebupent	pentamidine isethionate	pentamidine isethionate
niacin ER	niacin	niacin ER OTC, Slo-Niacin OTC
Omeppi	omeprazole/sodium bicarbonate	Zegerid OTC
orphenadrine-aspirin-caffeine	orphenadrine/aspirin/caffeine	chlorzoxazone, cyclobenzaprine HCl
phenazopyridine HCl	phenazopyridine HCl	AZO Urinary Pain Relief OTC
pseudoephedrine HCl	pseudoephedrine HCl	pseudoephedrine HCl OTC
ranitidine HCl	ranitidine HCl	cimetidine OTC, famotidine
Samsca	tolvaptan	tolvaptan
Transderm-Scop	scopolamine	scopolamine

C. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) Individual plans. A list of drugs included on the Essential Formulary, listed by therapeutic class, is available at https://client.formularynavigator.com/Search.aspx?siteCode=6571849149.

Table 1. Formulary Updates

(All formulary changes effective July 4, 2020, unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
MenQuadfi vaccine*	meningococcal (Groups A, C, Y, W) conjugate vaccine	3	A vaccine for the prevention of invasive meningococcal disease caused by *N. meningitides* serogroups A, C, W and Y in patients 2 years and older.
Isturisa	osilodrostat	4	An oral cortisol synthesis inhibitor for the treatment of patients with Cushing's disease.
Tukysa	tucatinib	4	For use in combination with trastuzumab and capecitabine for treatment of patients with advanced or metastatic HER2-positive breast cancer.
Items listed below were not added to the formulary			
Bafiertam*	monomethyl fumarate	NF	Aubagio, Gilenya, Mayzent
Milprosa vaginal ring*	progesterone vaginal ring	NF	Endometrin
Ongentys*	opicapone	NF	entacapone
Zeposia 0.92 mg Capsule, Starter Kit, and Starter Pack	ozanimod 0.92 mg Capsule, Starter Kit, and Starter Pack	NF	Gilenya, Mayzent
Koselugo 10 mg and 25 mg	selumetinib 10 mg and 25 mg	NF	Provider Discretion
Pemazyre	pemigatinib	NF	Provider Discretion
Sevenfact*	coagulation factor VIIa [recombinant]-jncw	NF	Provider Discretion

Formulary options: Tier 1, Tier 2, Tier 3, Tier 4, Non-formulary (NF).

*Effective date to be determined.

Table 2. Products to Be Removed or Shifted to Higher Tier –Effective October 1, 2020

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Afinitor	everolimus	everolimus
Daraprim	pyrimethamine	pyrimethamine
Diastat	diazepam	diazepam
Dyrenium	triamterene	triamterene
Halog	halcinonide	halcinonide
Moxeza	moxifloxacin HCl	moxifloxacin HCl
Naftin	naftifine HCl	naftifine HCl
Nebupent	pentamidine isethionate	pentamidine isethionate
Noxafil	posaconazole	posaconazole
Nuvaring	etonogestrel/ethinyl estradiol	Eluryng, etonogestrel-ethinyl estradiol
Orfadin	nitisinone	nitisinone
Samsca	tolvaptan	tolvaptan
Taclonex	calcipotriene/betamethasone	calcipotriene-betamethasone

Transderm-Scop	scopolamine	scopolamine
Travatan Z	travoprost	travoprost
Zortress	everolimus	everolimus

D. Changes to the Highmark Core Formulary

The Core Formulary is a closed formulary for select Commercial Individual plans. A list of drugs included on the Core Formulary, listed by therapeutic class, is available at https://client.formularynavigator.com/Search.aspx?siteCode=0874170847.

Table 1. Formulary Updates
(All formulary changes effective July 4, 2020 unless otherwise noted.)

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
MenQuadfi vaccine*	meningococcal (Groups A, C, Y, W) conjugate vaccine	3	A vaccine for the prevention of invasive meningococcal disease caused by *N. meningitides* serogroups A, C, W and Y in patients 2 years and older.
Isturisa	osilodrostat	4	An oral cortisol synthesis inhibitor for the treatment of patients with Cushing's disease.
Tukysa	tucatinib	4	For use in combination with trastuzumab and capecitabine for treatment of patients with advanced or metastatic HER2-positive breast cancer.
Items listed below were not added to the formulary			
Bafiertam*	monomethyl fumarate	NF	Tecfidera
Milprosa vaginal ring*	progesterone vaginal ring	NF	Endometrin
Ongentys*	opicapone	NF	entacapone
Zeposia 0.92 mg Capsule, Starter Kit, and Starter Pack	ozanimod 0.92 mg Capsule, Starter Kit, and Starter Pack	NF	Gilenya, Mayzent
Koselugo 10 mg and 25 mg	selumetinib 10 mg and 25 mg	NF	Provider Discretion
Pemazyre	pemigatinib	NF	Provider Discretion
Sevenfact*	coagulation factor VIIa [recombinant]-jncw	NF	Provider Discretion

Formulary options: Tier 1, Tier 2, Tier 3, Tier 4, Non-formulary (NF).
*Effective date to be determined.

Table 2. Products to Be Removed or Shifted to Higher Tier –Effective October 1, 2020

Brand Name	Generic Name	Preferred Alternatives
All Commercial Core Products		
adapalene	adapalene	tretinoin, Differin Gel OTC
Afinitor	everolimus	everolimus

Apriso	mesalamine	mesalamine ER
Bacitracin/Polymyxin	bacitracin zinc/polymyxin b	bacitracin/polymyxin OTC
Poly Bacitracin	bacitracin zinc/polymyxin b	bacitracin/polymyxin OTC
Depen	penicillamine	penicillamine
Kenalog	triamcinolone acetonide	triamcinolone acetonide
Lido-Sorb	lidocaine HCl	lidocaine 3% cream OTC
Nebupent	pentamidine isethionate	pentamidine isethionate
Nuvaring	etonogestrel/ethinyl estradiol	Eluryng, etonogestrel-ethinyl estradiol
orphenadrine-aspirin-caffeine	orphenadrine/aspirin/caffeine	chlorzoxazone, cyclobenzaprine HCl
Proglycem	diazoxide	diazoxide
Samsca	tolvaptan	tolvaptan
Silvadene	silver sulfadiazine	silver sulfadiazine
Tazorac	tazarotene	tazarotene
Zortress	everolimus	everolimus

E. Changes to the Highmark National Select Formulary

The National Select Formulary is an incentive formulary with a non-formulary drug list to manage products in therapeutic categories for which preferred alternatives are available. The National Select Formulary is available for select Commercial self-funded (ASO) plans. A list of drugs included on the National Select Formulary, listed by therapeutic class, is available at https://client.formularynavigator.com/Search.aspx?siteCode=3442182690.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (preferred)			
No changes at this time.			
Items listed below were added to the formulary (non-preferred)			
Pemazyre	pemigatinib	3	Provider Discretion
Tukysa	tucatinib	3	Tykerb
Isturisa*	osilodrostat	3	Provider Discretion
Koselugo*	selumetinib	3	Provider Discretion
Zeposia *	ozanimod	3	Gilenya, Mayzent
Bafiertam*	monomethyl fumarate	3	Tecfidera
MenQuadfi vaccine*	meningococcal (Groups A, C, Y, W) conjugate vaccine	3	Menactra
Milprosa vaginal ring*	progesterone vaginal ring	3	Crinone, Endometrin
Ongentys*	opicapone	3	entacapone
Sevenfact*	coagulation factor VIIa [recombinant]-jncw	3	Provider Discretion
Items listed below were not added to the formulary			
No changes at this time.			

Formulary options: Tier 1, Tier 2, Tier 3, Non-formulary (NF).
*Effective date and final formulary position to be determined.

Table 2. Additions to the Specialty Tier Copay Option
(Effective upon completion of internal review and implementation unless otherwise noted.)

Brand Name	Generic Name
Bafiertam	monomethyl fumarate
Tukysa	tucatinib
Zeposia	ozanimod
Isturisa	osilodrostat
Koselugo	selumetinib
Pemazyre	pemigatinib
Sevenfact	coagulation factor VIIa [recombinant]-jncw

F. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
ALK Targeting Kinase Inhibitors - Commercial and Healthcare Reform	TBD	Policy revised for Alunbrig (brigatinib) FDA-approved expanded indication in adults with first-line ALK-positive metastatic non-small cell lung cancer.
Anti-EGFR and HER2 Kinase Inhibitors - Commercial and Healthcare Reform	TBD	Policy revised to include newly FDA-approved kinase inhibitor: Tukysa (tucatinib). The member must be 18 years of age or older with a diagnosis of advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer. The member must use Tukysa in combination with trastuzumab and capecitabine and must have received one or more prior anti-HER2-based regimens in the metastatic setting.
Aubagio (teriflunomide) - Commercial and Healthcare Reform	TBD	Policy revised to include reauthorization criteria of provider attestation of disease stability, disease improvement, or delayed disease progression. Authorization duration changed to 24 months.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors - Commercial and Healthcare Reform	TBD	Policy revised for Braftovi (encorafenib) use in combination with cetuximab for metastatic colorectal cancer in adults with a documented BRAF V600E or V600K mutation, after prior therapy.
BTK Inhibitors - Commercial and Healthcare Reform	TBD	Policy revised for Imbruvica (ibrutinib) use in CLL/SLL for use as monotherapy or concurrent use with rituximab or obinutuzumab.
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	6/16/2020	Policy revised to include expanded indication for Taltz (ixekizumab) in members 6 years of age or older for the treatment of plaque psoriasis, to make Otezla (apremilast) preferred for psoriatic arthritis, and remove step through corticosteroid and immunosuppressants for ulcerative colitis.
Dupixent (dupilumab) - Commercial and Healthcare Reform	6/22/2020	Policy revised to allow coverage of Dupixent (dupilumab) in members that are 6 years of age or older for moderate to severe atopic dermatitis, have experienced therapeutic failure

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		to at least one corticosteroid (or have facial or anogenital involvement), and have experienced therapeutic failure to generic topical tacrolimus or pimecrolimus.
Rayos (prednisone) - Commercial and Healthcare Reform	6/18/2020	Policy revised to add reauthorization criteria requiring the prescriber to attest to positive clinical response to therapy. Policy revised to change the authorization duration from 12 months to 6 months.
Evekeo (amphetamine sulfate) - Healthcare Reform	6/18/2020	Policy revised to remove methamphetamine as a step for diagnosis of ADHD (Attention Deficit Hyperactivity Disorder) and to remove dexmethylphenidate and methamphetamine as steps for diagnosis of Narcolepsy. Policy revised to include requirement of adjunct reduced calorie diet and exercise for diagnosis of obesity.
Fertility - Commercial	BEST DATE	Policy revised to include new product Milprosa (progesterone) vaginal system requiring female gender, infertility diagnosis, using as part of an assisted reproductive technology (ART) treatment program, and has the ART/In Vitro Fertilization (IVF) medical benefit.
Fertility - Commercial NSF	BEST DATE	Policy revised to include new product Milprosa (progesterone) vaginal system requiring female gender, infertility diagnosis, using as part of an assisted reproductive technology (ART) treatment program, and has the ART/In Vitro Fertilization (IVF) medical benefit.
Fertility - Pennsylvania Healthcare Reform Individual Plans	BEST DATE	Policy revised to include new product Milprosa (progesterone) vaginal system requiring FDA approved indication and member is undergoing artificial insemination. Added approval criteria that Crinone can be approved when used for secondary amenorrhea, goal is to attain fertility, and member is undergoing artificial insemination. Authorization duration revised from 12 months to 6 months for infertility with a cumulative duration of 24 months, 1 month for secondary amenorrhea, and 6 weeks for cryptorchidism.
Fertility - Select Healthcare Reform Plans	BEST DATE	Policy revised to include new product Milprosa (progesterone) vaginal system requiring female gender, infertility diagnosis, using as part of an assisted reproductive technology (ART) treatment program, and has the ART/In Vitro Fertilization (IVF) medical benefit.
FGFR Kinase Inhibitors - Commercial and Healthcare Reform	TBD	Policy revised to include the newly FDA-approved kinase inhibitor Pemazyre (pemigatinib). Criteria includes age of 18 and older, FDA-approved diagnosis, appropriate fibroblast growth factor receptor (FGFR) fusion or rearrangement as detected by an FDA-approved test, and therapeutic failure or intolerance to 1 prior therapy for advanced or metastatic disease.
Fumarate Products - Commercial and Healthcare Reform	BEST DATE	Policy revised to include Bafiertam (monomethyl fumarate) with criteria of a relapsing form of multiple sclerosis.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Fumarate Products - Commercial and Healthcare Reform	TBD	Policy revised to include Bafiertam (monomethyl fumarate) with criteria of diagnosis of a relapsing form of multiple sclerosis, and if request is for Bafiertam (monomethyl fumarate) or Vumerity (diroximel fumarate), the member has experienced therapeutic failure or intolerance to Tecfidera (dimethyl fumarate), and reauthorization criteria of attestation of disease stability, disease improvement, or delayed disease progression.
Gattex (teduglutide) - Commercial and Healthcare Reform	6/18/2020	Policy revised to require a parenteral nutrition duration of at least 12 months for pediatric members. Policy revised to remove requirement of ability to ingest food for adults.
Gilenya (fingolimod) - Commercial and Healthcare Reform	6/17/2020	Policy revised to change reauthorization criteria to be provider attestation of disease stability, disease improvement, or delayed disease progression. Authorization duration changed to 24 months.
Hepatitis C Oral Agents - Commercial and Healthcare Reform	6/17/2020	Policy revised to include Epclusa's (sofobuvir/velpatasvir) expanded indication for pediatrics 6 years of age and older and specify creatinine clearance criteria for Vosevi (sofobuvir/velpatasvir/voxilaprevir) only.
Hepatitis C Oral Agents - Commercial Core	TBD	Policy revised to include Epclusa's (sofobuvir/velpatasvir) expanded indication for pediatrics 6 years of age and older and specify creatinine clearance criteria for Vosevi (sofobuvir/velpatasvir/voxilaprevir) only.
Daraprim (pyrimethamine) - Healthcare Reform	TBD	Revised policy to include reauthorization criteria.
Hepatitis C Oral Agents - Commercial National Select Formulary	TBD	Policy revised to include Epclusa's (sofobuvir/velpatasvir) expanded indication for pediatrics 6 years of age and older and specify creatinine clearance criteria for Vosevi (sofobuvir/velpatasvir/voxilaprevir) only.
Hereditary Angioedema - Commercial and Healthcare Reform	TBD	Policy revised to ensure that the prescriber submits documentation of member's weight for Berinert [C1 Esterase Inhibitor (Human)], Ruconest [C1 Esterase Inhibitor (Recombinant)], and Haegarda [C1 Esterase Inhibitor (Human)], the member is not on two acute therapies simultaneously for Berinert [C1 Esterase Inhibitor (Human)], Ruconest [C1 Esterase Inhibitor (Recombinant)], and Firazyr (icatibant), and the member is not on two prophylactic therapies simultaneously for Cinryze [C1 Esterase Inhibitor (Human)], Haegarda [C1 Esterase Inhibitor (Human)], and Takhzyro (lanadelumab-flyo).
Noxafil (posaconazole)- Commercial	6/18/2020	Policy revised to add reauthorization criteria for positive clinical response to therapy.
Isturisa (osilodrostat) - Commercial and Healthcare Reform	TBD	New policy created for Isturisa (osilodrostat); requires documentation of a diagnosis of Cushing's disease, age requirement of 18 years of age and older, prescribed by an endocrinologist, and documented failure of pituitary surgery or a contraindication to pituitary surgery. For reauthorization, must

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		submit mean urine free cortisol (mUFC) levels that are less htan or equal to the upper limit of normal (ULN) indicating response to treatment.
Cuvposa (glycopyrrolate) oral solution - Commercial	6/18/2020	Policy revised to include reauthorization criteria that the member has experienced a positive clinical resonse to therapy.
Mayzent (siponimod) - Commercial and Healthcare Reform	TBD	Policy revised to change authorization duration to 24 months.
MEK1/2 Kinase Inhibitors - Commercial and Healthcare Reform	TBD	New policy created for Koselugo (selumetinib) requiring age 2 years or older and diagnosis of neurofibromatosis type 1 with symptomatic, inoperable plexiform neurofibromas.
Miscellaneous Immunomodulators - Commercial and Healthcare Reform	TBD	Policy revised to include new indication for Pomalyst (pomalidomide) for Kaposi's sarcoma (KS); in AIDs related KS, after failure of highly active antiretroviral therapy (HAART) or in KS in patients who are HIV negative. Also, added new quantity limits necessary specifically for this new indication.
ALK, EGFR, FLT3 Kinase Inhibitors - Commercial and Healthcare Reform		Terminating policy: all criteria for Alunbrig has been added to the ALK, EGFR, FLT3 Kinase Inhibitors policy.
Obeticholic Acid Products - Commercial and Healthcare Reform	TBD	Policy revised to allow for anticipated approval of obeticholic acid in NASH fibrosis requiring age 18 years or older, diagnosis of NASH, fibrosis staging confirmed by liver biopsy, and NAFLD activity score.
Ongentys (opicapone) - Commercial and Healthcare Reform	BEST DATE	New policy created for Ongentys (opicapone) to ensure appropriate use in members with a diagnosis of Parkinson's disease, who will be using Ongentys as an adjunct to carbidopa/levodopa, who are experiencing wearing off (e.g., "off" episodes) between levodopa/carbidopa doses, and has experienced therapeutic failure, contraindication, or intolerance to entacapone and therapeutic failure or intolerance to two (2) of the following or contraindication to all of the following agents: rasagiline, pramipexole, ropinirole, or rotigotine.
Parathyroid Hormone Analogs - Commercial	TBD	Policy revised for Parathyroid Hormone Analogs to include authorized generic teriparatide requiring diagnosis and trial and failure of Tymlos in postmenopausal women at high risk fracture. Duration of therapy does not exceed 24 months with Forteo, teriparatide authorized generic, and Tymlos.
Parathyroid Hormone Analogs - Commercial National Select Formulary	TBD	Policy revised for Parathyroid Hormone Analogs to include authorized generic teriparatide requiring diagnosis and trial and failure of Tymlos in postmenopausal women at high risk fracture. Duration of therapy does not exceed 24 months with Forteo, teriparatide authorized generic, and Tymlos.
Parathyroid Hormone Analogs - Healthcare Reform	6/22/2020	Policy revised for Parathyroid Hormone Analogs to include authorized generic teriparatide requiring diagnosis and trial and failure of Tymlos in postmenopausal women at high risk fracture. Duration of therapy does not exceed 24 months with Forteo, teriparatide authorized generic, and Tymlos.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
PARP Kinase Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised for Zejula (niraparib) for use in adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy, per FDA-approved expanded indication; and for Lynparza (olaparib) for use in combination with bevacizumab for first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status, per FDA-approved expanded indication; and for Lynparza (olaparib) for use in adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer who have progressed following prior treatment with enzalutamide or abiraterone and who are concurrently receiving a gonadotropin-releasing hormone analog or who have had a bilateral orchiectomy, per FDA-approved expanded indication; and for Rubraca (rucaparib) for use in adults with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer who have been treated with androgen-directed therapy and taxane-based chemotherapy who are currently receiving a gonadotropin-releasing hormone analog or have had a bilateral orchiectomy, per FDA-approved expanded indication.
Risdiplam - Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate use of Risdiplam for spinal muscular atrophy type I, II, or III in patients with at least 2 copies of the survival motor neuron 2 gene with documentation of molecular genetic testing of 5q SMA confirming homozygous gene deletion, homozygous conversion mutation, or compound heterozygote, and documentation of motor function test results. Risdiplam should be prescribed by a neuromuscular specialist or neurologist and should not be taken with another SMN2 splicing modifier.
Synarel (nafarelin) - Commercial	TBD	Policy revised to require step through 2 standard of care treatments for endometriosis indication.
Synarel (nafarelin) - Healthcare Reform	TBD	Policy revised to add therapeutic failure, contraindication, or intolerance to at least 2 standard of care treatments for endometriosis: NSAIDs, combined hormonal contraceptive, progestin, and danazol.
Tegsedi (inotersen) - Commercial and Healthcare Reform	TBD	Policy revised to specify reauthorization criteria requiring Tegsedi (inotersen) to be prescribed by or in consultation with a neurologist or physician who specializes in the treatment of amyloidosis and the member to not be using other gene targeted therapy for the treatment o f hereditary transthyretin-mediated amyloidosis (hATTR). Policy revised to remove

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		requirement of that Tegsedi is not being used for sensorimotor or autonomic neuropathy that is unrelated to hATTR.
Topical Non-Steroid Therapy for Atopic Dermatitis - Healthcare Reform	6/22/2020	Policy revised to allow coverage of Eucrisa (crisaborole) in members that are 3 months of age or older, have a diagnosis of mild to moderate atopic dermatitis, have experienced therapeutic failure to at least two corticosteroids (or have facial or anogenital involvement) and have experienced therapeutic failure to generic topical tacrolimus or pimecrolimus.
Zeposia (ozanimod) - Commercial and Healthcare Reform	07/15/2020	New policy created to ensure appropriate of Zeposia (ozanimod) in members with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease who are 18 years of age and older and whose prescribing physician has recently (within 6 months) has documented: baseline electrocardiogram, liver transaminase and bilirubin, opthalmologic evalution if history of macular edema and/or uveitis, and complete blood count.

*For Commercial and Healthcare Reform policies, an exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
**All effective dates are tentative and subject to delay pending internal review or approval.

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Antimalarial Agents - Healthcare Reform	6/18/2020	Policy revised to align with CDC guidelines for the treatment of malaria.
Beta Blocker Management - Commercial	6/22/2020	Policy revised for Beta Blocker Management to elaborate that member has to try and fail 2 chemically-unique, preferred, generic beta-blockers or beta-blocker combinations. Added reauthorization criteria attesting positive response. Removed Sectral (acebutolol) from policy as off-market.
Doxepin 5% Cream - Healthcare Reform	TBD	Policy revised to change authorization duration from 3 months to 1 month.
Beta Blocker Management - Commercial National Select Formulary	TBD	Policy revised for Beta Blocker Management to elaborate that member has to try and fail 2 chemically-unique, preferred, generic beta-blockers or beta-blocker combinations for all non-preferred beta-blockers except Bystolic (nebivolol) and Byvalson (nebivolol; valsartan). For Bystolic and Byvalson elaborated that member has to try and fail 1 chemically-unique, preferred, generic beta-blocker or beta-blocker combination. Added reauthorization criteria attesting positive response. Removed Sectral (acebutolol) from policy as off-market.
Beta Blocker Management - Healthcare Reform	TBD	Policy revised for Beta Blocker Management to elaborate that member has to try and fail 2 chemically-unique, preferred, generic beta-blockers or beta-blocker combinations. Added

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		reauthorization criteria attesting positive response. Removed Sectral (acebutolol) from policy as off-market.
Bystolic (nebivolol) - Healthcare Reform Essential Formulary	6/18/2020	Policy revised for Bystolic (nebivolol) to elaborate that member has to try and fail 3 chemically-unique, preferred, generic beta-blockers or beta-blocker combinations.
Doxepin 5% Cream - Commercial	TBD	Updated authorization duration to 3 weeks.
Edarbi (azilsartan) - Healthcare Reform Essential Formulary	6/18/2020	Policy revised for Edarbi (azilsartan) to elaborate that member has to try and fail 2 chemically-unique, preferred, generic angiotensin receptor blockers.
Eucrisa (crisaborole) - Commercial	6/22/2020	Policy was revised to allow coverage of Eucrisa (crisaborole) in members that are 3 months of age or older, have a diagnosis of mild to moderate atopic dermatitis, and have experienced therapeutic failure to at least one corticosteroid. Reauthorization criteria was updated to ensure that the prescriber provides documentation or attestation of improvement or response to therapy.
Eucrisa (crisaborole) - Commercial Core	TBD	Policy revised to allow coverage of Eucrisa (crisaborole) in members that are 3 months of age or older, have a diagnosis of mild to moderate atopic dermatitis, and have experienced therapeutic failure to generic topical tacrolimus or pimecrolimus if 2 years of age or older. Reauthorization criteria was updated to ensure that the prescriber provides documentation or attestation of improvement or response to therapy.
Evekeo (amphetamine sulfate) - Commercial	TBD	Policy revised to remove methamphetamine as a step for diagnosis of ADHD (Attention Deficit Hyperactivity Disorder) and to remove dexmethylphenidate and methamphetamine as steps for diagnosis of Narcolepsy. Policy revised to include requirement of adjunct reduced calorie diet and exercise for diagnosis of obesity.
Lonhala Magnair (glycopyrrolate) - Commercial and Healthcare Reform	TBD	Policy revised to remove Seebri Neohaler (glycopyrrolate) from step therapy as it was removed from the market.
Lyrica (pregabalin) and Lyrica CR (pregabalin ER) - Commercial and Healthcare Reform	TBD	Policy revised to include reauthorization criteria that the member has experienced a positive clinical response to therapy. Automatic authorization criteria updated to reflect policy criteria of one claim for a medication used for the treatment of diabetes and one claim for a duloxetine product.
Non-Preferred Benign Prostatic Hyperplasia Therapy – Commercial and Healthcare Reform	TBD	Policy revised for Non-Preferred Benign Prostatic Hyperplasia to add criteria for Cardura's additional indication of hypertension and trial and failure of its generic doxazosin. Added brand Cialis (tadalafil) 2.5 mg as a target drug.
Non-Preferred Extended Release ADHD Products – Commercial and Healthcare Reform	TBD	New policy for non-preferred attention deficit hyperactivity disorder (ADHD) products including Adderall XR (amphetamine/dextroamphetamine ER), Adhansia XR (methylphenidate hydrochloride ER), Adzenys ER (amphetamine

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		ER), Adzenys XR-ODT (amphetamine ER), Aptensio XR (methylphenidate hydrochloride ER), Concerta (methylphenidate hydrochloride ER), Cotempla XR-ODT (methylphenidate ER), Daytrana (methylphenidate), Dexedrine Spansule (dextroamphetamine sulfate ER), Dyanavel XR (amphetamine ER), Focalin XR (dexmethylphenidate hydrochloride ER), Jornay PM (methylphenidate hydrochloride ER), Mydayis (amphetamine/dextroamphetamine ER), Quillichew ER (methylphenidate hydrochloride ER), Quillivant XR (methylphenidate hydrochloride ER), Relexxii (methylphenidate hydrochloride ER), Ritalin LA (methylphenidate hydrochloride ER). When used for ADHD, requirements include FDA labeled indication, FDA approved age, therapeutic failure, intolerance, or contraindication to Vyvanse (lisdexamfetamine) and 2 preferred generic agents (dexmethylphenidae ER, dextroamphetamine/amphetamine ER, dextroamphetamine ER, or methylphenidate ER), or for Adzenys ER, Adzenys XR-ODT, Cotempla XR-ODT, Daytrana, Dyanavel XR, Quillichew ER, or Quillivant XR patient must have inability to swallow tablets. When used for narcolepsy, requirements include FDA approved indication, FDA approved age, confirmation of narcolepsy by cerebrospinal fluid hypocretin, multiple sleep latency test, and/or polysomnography, and therapeutic failure, contraindication, or intolerance to dextroamphetamine sulfate ER capsules. Reauthorization criteria of attestation of positive clinical response to therapy.
Non-Preferred Glucagon-Like Peptide-1 Receptor Agonists – Commercial and Healthcare Reform	BEST DATE	Policy revised to allow Rybelsus (semaglutide) as an option for trial and failure for approval of a non-preferred GLP-1 receptor agonist. Policy revised to allow taking a non-preferred GLP-1 receptor agonist in addition to metformin.
Non-Preferred Immediate Release ADHD Products – Commercial and Healthcare Reform	TBD	New policy for non-preferred attention deficit hyperactivity disorder (ADHD) products including Adderall (dextroamphetamine/amphetamine), Desoxyn (methamphetamine hydrochloride), Evekeo (amphetamine sulfate), Evekeo ODT (amphetamine sulfate orally disintegrating tablet), methylphenidate hydrochloride chewable tablet, ProCentra (dextroamphetamine sulfate), Ritalin (methylphenidate hydrochloride), and Zenzedi (dextroamphetamine sulfate). When used for ADHD, requirements include FDA labeled indication, FDA approved age, therapeutic failure, intolerance or contraindication to Vyvanse (lisdexamfetamine) and 2 preferred generic agents (dexmethylphenidate, dextroamphetamine/amphetamine, dextroamphetamine, and methylphenidate), or for ProCentra, Evekeo ODT, and Methylphenidate chewable tablets patient must have inability to swallow. When used for narcolepsy, requirements include FDA approved indication, FDA approved age, confirmation of

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		narcolepsy by cerebrospinal fluid hypocretin, multiple sleep latency test, and/or polysomnography, therapeutic failure, intolerance, or contraindication of 2 preferred generic products (dextroamphetamine/amphetamine, dextroamphetamine, and methylphenidate), or for methylphenidate chewable tablets and ProCentra the patient must have an inability to swallow tablets. Reauthorization criteria for ADHD and Narcolepsy of attestation that the member has experienced positive clinical response to therapy.
Non-Preferred Sodium-Glucose Co-Transporter 2 Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised to add new indication for Farxiga (dapagliflozin). Member must have diagnosis of New York Heart Association II, III, or IV heart failure without concurrent type 2 diabetes. Member has left ventricular ejection fraction ≤ 40%. Member is using Farxiga in combination with an angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, or Entresto unless all are contraindicated.
Tirosint-SOL - Commercial and Healthcare Reform	TBD	Policy revised to require documentation that the member has experienced positive clinical response to therapy for reauthorization. Policy revised to remove trial and failure requirement of levothyroxine for reauthorization.
Topical Antifungals-Commercial and Healthcare Reform	6/18/2020	Policy revised to account for age for Kerydin and to reflect new age expansion for Jublia. For Kerydin, added criterion to confirm member age 18 and older. For Jublia, clarified appropriate alternatives based on patient age - for members between the ages of 6 and 12, no therapeutic alternatives are required; for members between the ages of 12 and 18, member has to try and fail ciclopirox 8% topical solution; and members 18 and older must try and fail both ciclopirox 8% topical solution and generic oral terbinafine.
Topical Corticosteroids – Commercial and Healthcare Reform	TBD	Policy revised to include Halog (halcinonide) topical solution as a new target.
Yupelri (revefenacin) - Commercial and Healthcare Reform	TBD	Policy revised to remove Seebri Neohaler (glycopyrrolate) from step therapy as it was removed from the market.
Zerviate (cetirizine ophthalmic solution) 0.24% - Commercial and Healthcare Reform	BEST DATE	New policy created for Zerviate (cetirizine ophthalmic solution) requiring FDA-approved indication and step through generic olopatadine.

*For Commercial and Healthcare Reform policies, an exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
All effective dates are tentative and subject to delay pending internal review or approval.
Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

3. Formulary Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria
General Non-Formulary Request Criteria - Delaware NSF and PA and WV NSF	TBD	Policy revised to include the upcoming 7/1/20 changes to the targeted medications and alternatives for the National Select formulary within Table 1.

*All effective dates are tentative and subject to delay pending internal review or approval.

4. Quantity Level Limit (QLL) Programs*

(Effective immediately upon completion of internal review and implementation, unless otherwise noted.)

Table 1. Quantity Level Limits – Quantity per Duration for Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Pemazyre (pemigatinib)	14 tablets per 16 days	42 tablets per 48 days
Pomalyst 1 mg, 2 mg, 3 mg, and 4 mg	21 caps per 21 days	63 capsules per 63 days
Trulicity 0.75 mg/0.5 mL	2 mL per 21 days	6 mL per 63 days
Trulicity 1.5 mg/0.5 mL	2 mL per 21 days	6 mL per 63 days
Zeposia (ozanimod) 0.23-0.46 mg Starter Pack	1 pack per 365 days	1 pack per 365 days
Zeposia (ozanimod) 0.23-0,92 mg Starter Pack	1 pack per 365 days	1 pack per 365 days

*Effective date to be determined.

Table 2. Quantity Level Limits – Quantity per Dispensing Event – Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Halog (halcinonide) 0.1% Solution*	120 mL	120 mL

*Effective date to be determined.

Quantity per dispensing event limits the quantity of medication that can be dispensed per each fill. If the submitted day supply on a claim is 34 days or less, the retail limit will apply. If the submitted day supply on a claim is greater than 34 days, the mail limit will apply.

Table 3. Maximum Daily Quantity Limits – Commercial and Healthcare Reform Plans

Drug Name	Daily Limit
Bafiertam (monomethyl fumarate)*	4 capsules per day
Koselugo (selumetinib) 10 mg	8 capsules per day
Koselugo (selumetinib) 25 mg	4 capsules per day
Ongentys (opicapone)*	1 tablet per day
Tukysa (tucatinib)	4 tablets per day
Zeposia (ozanimod) 0.92 mg Capsule	1 capsule per day

*Quantity per Duration (QD) rule also applies to this medication (refer to Table 1).
Members can receive up to the maximum day supply according to their benefits, but the daily limit must not be exceeded for each individual day.

Requests for coverage of select medications exceeding the defined quantity level limits may be submitted for clinical review. Maximum-day supply on certain medications may vary depending on member's benefit design.

SECTION II. Highmark Medicare Part D Formularies

A. Changes to the Highmark Medicare Part D 5-Tier Incentive Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare Part D Formularies online at:

Performance Formulary: http://client.formularynavigator.com/Search.aspx?siteCode=0881624036

Venture Formulary: http://client.formularynavigator.com/Search.aspx?siteCode=0879201750

Incentive Formulary: http://client.formularynavigator.com/Search.aspx?siteCode=0876593134

Table 1. Non-Preferred Products
(Effective immediately pending Centers for Medicare and Medicaid Services (CMS) approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Preferred Alternatives
Ongentys	opicapone	entacapone
MenQuadfi vaccine	meningococcal (Groups A, C, Y, W) conjugate vaccine	Provider Discretion

B. Changes to the Highmark Medicare Part D 5-Tier Closed Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare Part D Formularies online at:

Performance Formulary: http://client.formularynavigator.com/Search.aspx?siteCode=0881624036

Venture Formulary: http://client.formularynavigator.com/Search.aspx?siteCode=0879201750

Incentive Formulary: http://client.formularynavigator.com/Search.aspx?siteCode=0876593134

Table 1. Non-Preferred Products
(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Preferred Alternatives
Ongentys	opicapone	entacapone
MenQuadfi vaccine	meningococcal (Groups A, C, Y, W) conjugate vaccine	Provider Discretion

C. Additions to the Specialty Tier

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name
Bafiertam	monomethyl fumarate
Darzalex Faspro	daratumumab/hyaluronidase-fihj
Durysta	bimatoprost
Fensolvi kit	leuprolide acetate kit
Isturisa	osilodrostat
Jelmyto	mitomycin
Koselugo 10 mg and 25 mg	selumetinib 10 mg and 25 mg
Pemazyre	pemigatinib
Trodelvy	sacituzumab govitecan-hziy
Tukysa	tucatinib
Zeposia 0.92 mg Capsule	ozanimod 0.92 mg Capsule
Zeposia 7-Day Starter Kit (Pack)	ozanimod 7-Day Starter Kit (Pack)

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
ALK Targeting Kinase Inhibitors - Medicare	TBD	Policy revised for Alunbrig (brigatinib) FDA-approved expanded indication for first-line ALK-positive metastatic non-small cell lung cancer.
ALK, EGFR, FLT3 Kinase Inhibitors - Medicare	TBD	Terminating policy: all criteria for Alunbrig has been added to the ALK, EGFR, FLT3 Kinase Inhibitors policy. CAN TERM WITH J-878 POST.
Anti-EGFR and HER2 Kinase Inhibitors – Medicare	TBD	Policy revised to include newly FDA-approved kinase inhibitor: Tukysa (tucatinib). The member must be 18 years of age or older with a diagnosis of advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer. The member must use Tukysa in combination with trastuzumab and capecitabine and must have received one or more prior anti-HER2-based regimens in the metastatic setting.
Antipsychotics - Medicare	TBD	Policy revised for Atypical Antipsychotics to include Caplyta (lumateperone) and criteria for approval; administrative changes.
BRAF Mutation-Targeting & MEK1/2 Kinase Inhibitors - Medicare	TBD	Policy revised for Braftovi (encorafenib) use in combination with cetuximab for metastatic colorectal cancer with a documented BRAF V600E or V600K mutation, after prior therapy.
BTK inhibitors - Medicare	TBD	Policy revised for Imbruvica (ibrutinib) use in CLL/SLL for use as monotherapy or concurrent use with rituximab or

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		obinutuzumab.
Chronic Inflammatory Diseases - Medicare	TBD	Policy revised to include expanded indication for Taltz (ixekizumab) in members 6 years of age or older for the treatment of plaque psoriasis and to remove step through corticosteroid and immunosuppressants for ulcerative colitis.
Daraprim (pyrimethamine) - Medicare 2021 FUTURE STATE	TBD	New policy created for Daraprim requiring FDA-approved indication and step through generic trimethoprim-sulfamethoxazole and generic pyrimethamine.
Darzalex (daratumumab) and Darzalex Faspro (daratumumab and hyaluronidase-fihj) - Medicare	TBD	Policy revised to add approval criteria for Darzalex (daratumumab) for use in combination with lenalidomide and dexamethasone in newly diagnosed patients with multiple myeloma ineligible for autologous stem cell transplant. Policy revised to add approval criteria for Darzalex Faspro (daratumumab and hyaluronidase-fihj) based on FDA approved indications.
Dupixent (dupilumab) - Medicare	TBD	Policy revised to include expanded indication for Dupixent (dupilumab) in members 6 years of age or older for moderate to severe atopic dermatitis.
Durysta (bimatoprost) Implant - Medicare	TBD	New policy for Durysta (bimatoprost) implant to ensure a appropriate diagnosis, trial and failure of generic latanoprost and one other generic ophthalmic alternative that lowers intraocular pressure, and the prescriber provides documentation of which eye the implant will be administered and that the specified eye has not received a Durysta (bimatoprost) implant previously.
Epidiolex (cannabidiol solution) - Medicare	TBD	Policy revised to change the standard of care treatments for Lennox-Gastuat Syndrome to lamotrigine and clobazam.
Eucrisa (crisaborole) - Medicare	TBD	Policy was revised to allow coverage of Eucrisa (crisaborole) in members that are 3 months of age or older, have a diagnosis of mild to moderate atopic dermatitis, have experienced therapeutic failure to at least one corticosteroid, and have experienced therapeutic failure to generic topical tacrolimus or pimecrolimus.
FGFR Kinase Inhibitors - Medicare	TBD	Policy revised to include the newly FDA-approved kinase inhibitor Pemazyre (pemigatinib). Criteria includes age of 18 and older, FDA-approved diagnosis, appropriate fibroblast growth factor receptor (FGFR) fusion or rearrangement as detected by an FDA-approved test, and therapeutic failure or intolerance to 1 prior therapy for advanced or metastatic disease.
Fumarate Products - Medicare	TBD	Policy revised to include Bafiertam (monomethyl fumarate) with criteria of diagnosis of a relapsing form of multiple sclerosis.
High Risk Medications in the Elderly - Medicare	TBD	Policy revised to remove glimepiride as a non-high risk alternative for glyburide.
Homozygous Familial Hypercholesterolemia - Medicare	TBD	Policy revised for Homozygous Familial Hypercholesterolemia to remove Kynamro (mipomersen) as it is off-market without an RxCUI. Removed all mention of Kynamro from criteria.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Isturisa (osilodrostat) - Medicare	TBD	New policy created for Isturisa (osilodrostat); requires documentation of a diagnosis of Cushing's disease, age requirement of 18 years of age and older, and documented failure of pituitary surgery or a contraindication to pituitary surgery. For reauthorization, must submit mean urine free cortisol (mUFC) levels that are less htan or equal to the upper limit of normal (ULN) indicating response to treatment.
MEK1/2 Kinase Inhibitors - Medicare	TBD	New policy created for Koselugo (selumetinib) requiring age 2 years or older and diagnosis of neurofibromatosis type 1 with symptomatic, inoperable plexiform neurofibromas.
Miscellaneous Immunomodulators - Medicare	TBD	Policy revised per FDA-approved expanded indication for Pomalyst (pomalidomide) in Kaposi sarcoma (KS) for adults with AIDS-related KS after failure of highly active antiretroviral therapy (HAART), or in patients with KS who are HIV negative.
Obeticholic Acid Products - Medicare	TBD	Policy revised to allow for anticipated approval of obeticholic acid in NASH fibrosis requiring age 18 years or older, diagnosis of NASH, fibrosis staging confirmed by liver biopsy, and NAFLD activity score.
Ongentys (opicapone) - Medicare	TBD	New policy created for Ongentys (opicapone) to ensure appropriate use in members with a diagnosis of Parkinson's disease, who will be using Ongentys as an adjunct to carbidopa/levodopa, who are experiencing wearing off (e.g., "off" episodes) between levodopa/carbidopa doses, and has experienced therapeutic failure, contraindication, or intolerance to entacapone and therapeutic failure or intolerance to one (1) of the following or contraindication to all of the following agents: rasagiline, pramipexole, ropinirole, or rotigotine.
Parathyroid Hormone Analogs - Medicare	TBD	Policy revised for Parathyroid Hormone Analogs to include authorized generic teriparatide requiring diagnosis and trial and failure of Tymlos in postmenopausal women at high risk fracture. Duration of therapy does not exceed 24 months with Forteo, teriparatide authorized generic, and Tymlos.
PARP Kinase Inhibitors – Medicare	TBD	Policy revised for Zejula (niraparib) for use in adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy, per FDA-approved expanded indication; and for Lynparza (olaparib) for use in combination with bevacizumab for first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status, per FDA-approved expanded indication; and for Lynparza (olaparib) for use in adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		who have progressed following prior treatment with enzalutamide or abiraterone and who are concurrently receiving a gonadotropin-releasing hormone analog or who have had a bilateral orchiectomy, per FDA-approved expanded indication; and for Rubraca (rucaparib) for use in adults with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer who have been treated with androgen-directed therapy and taxane-based chemotherapy who are currently receiving a gonadotropin-releasing hormone analog or have had a bilateral orchiectomy, per FDA-approved expanded indication.
Programmed Death Receptor Therapies - Medicare	TBD	Policy revised per FDA-approved expanded indications for: Imfinzi (durvalumab) use in first-line treatment for extensive-stage small cell lung cancer (ES-SCLC) in combination with etoposide and either carboplatin or cisplatin; and for Opdivo (nivolumab) use in adult patients with metastatic non-small cell lung cancer expressing PD-L1 (programmed death-ligand 1) as determined by an FDA-approved test, with no EGFR (epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genomic tumor aberrations, as first line treatment in combination with Yervoy (ipilimumab); and for Opdivo (nivolumab) in combination with Yervoy (ipilimumab) and 2 cycles of platinum doublet chemotherapy, for first line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC), with no EGFR (epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genomic tumor aberrations.
Tecentriq (atezolizumab) – Medicare	TBD	Policy revised per FDA-approved expanded indications for Tecentriq (atezolizumab) for use in adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression with no EGFR (epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genomic tumor aberrations; and for Tecentriq (atezolizumab) in combination with Avastin (bevacizumab) for the treatment of unresectable or metastatic hepatocellular carcinoma (HCC) with no prior systemic therapy.
Testosterone (Androgens) - Medicare	TBD	Policy revised to allow use of testosterone enanthate products for delayed puberty in males.
Trodelvy (sacituzumab govitecan) - Medicare	TBD	Policy created for Trodelvy (sacituzumab govitecan-hziy) for use in adults with metastatic triple-negative breast cancer after at least two prior therapies for metastatic disease.
Zeposia (ozanimod) - Medicare	TBD	New policy created to ensure appropriate of Zeposia (ozanimod) in members with relapsing forms of multiple sclerosis who are 18 years of age and older and whose prescribing physician has recently (within 6 months) has documented: baseline electrocardiogram, liver transaminase and bilirubin, opthalmologic evaluation if history of macular

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		edema and/or uveitis, and complete blood count.

*All effective dates are tentative and subject to delay pending internal review or approval.

2. Managed Prescription Drug Coverage (MRxC) Program *

No changes at this time.

3. Quantity Level Limit (QLL) Program*

(Effective date pending CMS approval, completion of internal review and implementation, unless otherwise noted.)

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Bafiertam (monomethyl fumarate)	4 capsules per day	4 capsules per day
Koselugo (selumetinib) 10 mg	8 capsules per day	8 capsules per day
Koselugo (selumetinib) 25 mg	4 capsules per day	4 capsules per day
Ongentys (opicapone)	1 tablet per day	1 tablet per day
Pemazyre (pemigatinib)	14 tablets per 21 days	14 tablets per 21 days
Tukysa (tucatinib)	4 tablets per day	4 tablets per day
Zeposia (ozanimod) 0.92 mg Capsule	1 capsule per day	1 capsule per day
Zeposia (ozanimod) 7-Day Starter Kit	1 kit per 365 days	1 kit per 365 days
Zeposia (ozanimod) 7-Day Starter Pack	1 pack per 365 days	1 pack per 365 days

Add any drug-specific information/exceptions in footnotes

All effective dates are tentative and subject to delay, pending CMS approval, internal review, and implementation.